contraction, not .4 percent, not four percent, but 40 percent, and I've got it on a video that CBC did when they interviewed me on their show called "Marketplace."

This means multiple surgeries for implant patients. How did this statistics grow from .4 percent to 40 percent in three years? Do we even know what accurate statistics are in this area? I think not.

Now I'm going to tell you about my real troubles. I could live with the sacrifice of the loss of sensation in my breast. I can live with my and my husband's dissatisfaction over the appearance of my implanted breasts. But I could not live without my health.

Four months after the initial surgery, I became sick with flu-like illnesses that lasted for months on end. During that time I had pneumonia, bronchitis and extreme fatigue. I would start to recover, but then would get sick again only days later.

Over the next year I felt exhausted all

the time. I used to stay up until at least midnight previously, but now I'd fall into bed with exhaustion by nine o'clock at night.

Some days were worse than others, but not a day went by without a general feeling of fatigue and illness.

Another symptom was sleep disturbance since I would wake up two to three times a night soaking wet with perspiration. They call these night sweats.

In January of 1997, I became ill again with bronchitis-pneumonia for three months. On many occasions, I had such sharp chest pain that I lost my breath and was unable to move. I also began to have difficulty concentrating and often felt spaced out.

Then in April of 1997, I woke up one morning. I went to the wash room, and the toilet was filled with blood. Now, this wasn't a slight pink color, but it deep red. It was pure blood. I remember being so horrified that this happened I jumped in my car. I was on my cell phone. I was sobbing all the way to the doctor's office, and they

said, "Oh, you've probably got a bladder infection."

I had had a couple of bladder infections in the past. I had never peed pure blood before, and it continued to happen after that.

A week later, I went for an ultrasound for the lumps in my breast and chest pain. The ultrasound apparently showed nothing. I had never previously had any lumps in my breasts. The doctor had no explanation, and I felt I had hit a brick wall with the medical establishment.

In the summer of 1997, I began to experience debilitating joint pain. My left hand was so stiff and was aching that I could not clinch my fingers. I felt like I had arthritis in my left hand and arm. I have no history of this disease on either side of my family.

I mean, I know I could go on forever. I'll try to sum it up. I had the saline implants removed in January of 1998. I have not been sick since then. I still have night sweats. Otherwise I don't have anymore chest pain. I have a very strong constitution, which is what I had before, and the only

thing I have to deal with now is the way I look, and it's taken me two years to have the confidence to date again because my husband left me. He could not go through this with me.

I have three children, ages five, seven, and nine, and I am producing a video on body image to take to all of the high schools across North America.

I also am the founder of the Women's Investment Network. So if you want any good stock tips, just see me after.

You know, I'm a very capable and I consider myself a very smart woman. I went to university at the age of 16 and all the rest of it, and this was the most stupidest thing I ever did, was to do this because I believed the professionals, and whatever.

I have pages here that I wrote. I think the media is afraid to say anything because of where their funding comes from, and I think the Internet is the best thing that ever happened to women in this situation because they can finally be heard without any filters, and that's why most of the people in this

room have given their testimony, because they've gotten on the Internet. They've become educated, and they're here today.

And I thank you very much for this opportunity.

CHAIRMAN WHALEN: Thank you, Ms. Angus.

Ms. McGinn.

MS. McGINN: Good morning. My name is Maura McGinn, and I'd like to thank you, Mr. Chairman, and the other members of the panel this morning for the opportunity to appear before you today.

Let me start by answering the questions like everybody else you asked of the witnesses at today's hearing. First, I am a professional actor and model who is appearing before you today representing only myself.

Second, I have no financial or other professional ties to any saline filled breast implant manufacturer or industry association.

Third, I am paying personally for all travel and other expenses related to my participating in this hearing.

Fourth, I am not a party to any pending lawsuit relating to breast implants.

And finally, I do not now, nor have I ever derived income of any kind from surgical procedures using breast implants or from treating patients with complaints they believe that are related to breast implants.

Why then am I here today? Because it is important that you hear from more than industry representatives who only have financial interests in the income and from researchers whose interest in the subject is merely academic.

You also need to hear from people like me, breast cancer survivors whose lives have been and will continue to be affected directly and immediately by the recommendation you make.

I want to assure you that while I am a professional actor, I am not acting this morning. My words and the emotions that prompt them are quite real and sincere.

I support fully any and every decision that will add to the information available to patients

about the benefits and risks of saline filled breast implants, in much the same way that I wanted to know everything possible about the efficacy of the different treatment options I had when my cancer was diagnosed. I also want to know everything there was to know about the different options available for reconstruction.

I want to state this as clearly as it can be stated. Manufacturers of saline filled breast implants must be required to do all the research needed to assure people like me about their safety. The fact that these devices have already been implanted in my body does not diminish in any way my need to know that they are safe.

Anyone who is either already using saline filled breast implants or who will be faced with the decision in the future about using them is not just entitled to this information, but should be guaranteed that it will be provided.

My case may be instructive. Unlike other breast cancer patients, I chose not to be reconstructed immediately. In fact, I waited six

years before making the decision to have additional surgery.

Why did I wait so long? Well, part of the reason was that I wanted to focus all of my emotional and intellectual energy on my treatment. Also, part of the reason was, frankly, I was not sure I was going to be around. But at least -- I am thankfully.

But at least an equal part of the reason was that I was not convinced about the safety of breast implants. At the time I was diagnosed with cancer, silicone gel implants had become very controversial, and I did not want to wade into those troubled waters, given what I was hearing, what my doctor was telling me, and my own research.

Six years later my research, combined with my doctor's advice and counsel, led me to my decision to use saline filled implants. Although the information about saline filled implants was limited to and often more conjecture than fact, nothing I had read or heard and no experience that I have had so far has come close to convincing me that my decision was incorrect.

To the contrary, my decision to be reconstructed has had a huge positive impact on my life. Because I am happier with the way I look, I am also happier with who I am.

I know that there are those who say that my appearance should not matter, and in some sense they are right, but they're also wrong. I know from personal experience that for me at least, and I suspect millions of other women as well, how I look strongly affects how I feel and how I relate to others.

A moment ago I said I support all efforts, like those being considered by this panel, that will add to the information available to patients about the benefits and risks of saline filled breast implants. Anything the FDA can do to add to the base of knowledge about these implants, including continuing to vigorously implement the PMA process, should, indeed, must go forward.

The more comprehensive the research manufacturers are required to do and the more widespread they are forced to disseminate the

findings, the better. There's no justifiable excuse for this not being the case.

I also want to make it clear, however, that the ultimate decision about assuming the risk of using saline filled implants must continue to be left to people like me, the cancer survivors whose lives will be affect by whether or not they are reconstructed.

Unless there is incontrovertible evidence that saline filled implants are unsafe, breast cancer patients must continue to be allowed to obtain them. Make sure that all the research is done. Make sure that the research is conducted properly, and please let us know about the suspected risks and concerns.

But do not ever allow the decision about whether I can use them to be made by someone other than me. And that includes all of the members of this panel, the FDA as a whole, the implant manufacturers, or anyone on Capitol Hill who knows -- who think they know more about my body than I do.

Thank you.

CHAIRMAN WHALEN: Thank you.

And Ms. Duhala.

MS. DUHALA: Good morning, ladies and gentlemen. My name is Karen. I'm 38 years old. I have been happily married for 14 years and the mother of two children, a daughter who is eight and a son who is six years old, and I hold a full-time working position.

I am here today to share my experience regarding my own decision to have breast implant surgery. I have personally paid for my travel expenses incurred to attend this hearing. I do not have any financial ties with breast implant manufacturers, and I have never been, nor am I currently involved as a witness in any lawsuits involving breast implants.

I am, however, an office manager for a plastic surgeon, a solo practitioner in the Baltimore, Maryland area. I have been employed with the plastic surgeon for the past six years, and being that he does perform breast augmentation, along with many other cosmetic procedures, a portion of my salary is derived from breast augmentation surgery.

I'm using my own personal vacation time today to cover the missed day at work.

When originally reading about the hearing today regarding saline filled breast implants, I did, in fact, speak with many former patients to see if they would come and share their own experiences with you. Most declined because, quite frankly, I could not guarantee their confidentiality.

I, too, like my privacy, but with respect to the past silicone breast implant controversy, the fact that most people do not like to talk about their private lives and their private decisions in the public eye and the fact that I have had a very positive experience, and my decision has affected me in a positive way, I thought it was important for me to come and to speak.

When thinking about what I was going to say today, first I went through all the statistics and I read all of the articles on the studies back from the silicone breast implants and how far we've come, and then I redirected my focus onto patients that I came across through the practice with my six years of

employment, and I began jotting down their stories.

And what I found is that I am one of the patients. I, too, fit the category of the patients that we often see.

Almost all of our patients have been embarrassed by the way they look. They feel guilty about coming to a plastic surgeon and expressing how they feel. They worry about what other people will think. They're not vain. These are women who are in their late 20s to the early 40-ish age bracket. A large percentage are married with children. They're involved with schools and PTA and church organizations, civic organizations, and hold jobs. They're educated women who are making choices.

When meeting with patients in consultations, some of the women who make their decisions after meeting with the doctor that I work for, they decide not to undergo breast augmentation, breast implant surgery.

Other patients we elect to not do the surgery on, and, yes, there are those many that do elect to have the surgery and do have.

I had personally contemplated having a breast enlargement for many, many years. Years of humiliation go back as far as high school. I can still vividly remember the teasing by my friends and, oh, yes, by my family members, too; the feeling of humiliation when wearing certain clothes, let alone a bathing suit.

Please don't misunderstand me. I have never lacked self-confidence, and I feel that for the most part I'm a well rounded individual, but I, too, was self-conscious about the way I felt and in the way I looked. I avoided certain places in certain situations.

Having the surgery has not changed my life,b ut it has given me a personal boost. That is, when I walk, I walk with my back a little bit straighter, and I hold my head up a little higher. I feel better about myself.

I wish I could explain passionately what the impact has done for me, but I can't find the words. It's funny because my husband was dead set against my having this surgery. He thought I was

crazy. When making my decision, I was like many others. I was reluctant. I was worried about what my family would say, what my friends would say, what my church affiliations would think, let alone the guilt of spending so much money on myself.

Would I be giving the wrong message to my two young children about really what's important in life? Shouldn't I be saving my money for the braces and the college education?

But with all of that said, the most important thing to me was it was my decision. It was my choice.

As in primarily all aspects of my life thus far, I have made personal choices, and with almost all of my choices, there are associated risks and responsibility.

I made the choice to drive, and even though I'm well educated, I went through driver's education training; I read my AAA magazine on the driver tips. I have even taken auto mechanics class to learn how to check air pressure and my oil. I still know the risk that any day I could be involved

in an automobile accident.

I made the choice to have children. There were risks involved with childbirth and risks that my children would not be born so-called normal. Some of the risks were known and presented to me. Others were not, and although I received excellent prenatal care and followed my doctor's orders, no one could prevent nor no one could predict that my son would be born a bilateral cleft lip and palate baby.

I smoke. I know the risks. I'm fully aware that my smoking will some day cause my death more than likely.

My point is that breast augmentation is a choice. Like almost everything else, surgical or nonsurgical, there are choices, risks and responsibilities.

My personal experience was that I was well informed of the risks both of undergoing a surgical procedure using general anesthesia and the risk of breast implants themselves. It was my choice. I accepted the risks, and I still accept the risks that there may be complications down the road.

My choice to have breast augmentation was one of the best choices I have made personally in my life for my own self. I strongly feel that as long as women are educated about the benefits and the risks, it should be a woman's choice.

It is also my opinion that today, between the implant manufacturers, the ASPS, and the doctor's responsibility of his or her addressing the pros and cons to every surgical procedure they perform, breast implants or otherwise, that patients are well informed today.

I sometimes feel like we --

CHAIRMAN WHALEN: Excuse me. Could you come to a conclusion, Ms. Duhala?

MS. DUHALA: I can.

-- that we as a practice scare patients, and I'll just sum it up.

It was one of the best decisions. I would like to share and I'm going to leave this with you. When our patients come to our practice, because some people were talking about breast feeding and the four percent of risks, the information that we give out,

and I work for a Board certified plastic surgeon, it is noted that it is 20 to 40 percent of patients do run the risks of the capsular contracture, and it's all in this booklet.

Also, there's an informed consent that we have. It's a four page informed consent about the risks, and it does stress that for certain things as far as breast feeding children, there is no studies that shows that it is or is not dangerous, and that is written out.

And that's the biggest thing. I feel that the most important thing in making a decision to have any cosmetic surgery is to have a good doctor who will educate you and give you all of the information, and with the Internet today, I agree. The information is too available if the doctor is not willing to do that, but check your doctor out, and somewhat evaluate your doctor as your doctor is evaluating you.

Thank you.

CHAIRMAN WHALEN: Thank you.

I believe all of the individuals who had been scheduled have now had time at the podium, and

before we proceed to the consumer groups, we'll take a ten minutes break.

(Whereupon, the foregoing matter went off the record at 10:06 a.m. and went back on the record at 10:21 a.m.)

DR. KRAUSE: If everybody could please start getting back to your seats, we could go on with the meeting. Thank you.

CHAIRMAN WHALEN: If everyone will please take a seat, we'll try to resume, and we're going to be proceeding to the presentations of consumer groups and consumer information providers with the critical distinction now being that ten minutes are allotted to each of the presenters, and I would remind each of the presenters to again please try to be as fastidious as the individuals were in terms of noting the time. When the yellow light begins to flash, it is key that you begin to sum up, and if the red light flashes, then please come to a conclusion.

If there were any of the individuals who had been previously identified who showed up late who would still like to address the panel, if you could

please identify yourself to the FDA, then we will try to get you in if we can.

The first listed consumer group, consumer information provider is Ms. Nicole Cummings from Implantinfo.com

MS. CUMMINGS: Good morning, ladies and gentlemen. My name is Nicole, and like many of the women that will speak before you this week, I, too, have breast implants.

However, in addition to being a breast augmentation patient, I think I bring much broader perspective to the issue before you. I host a Web site at www.implantinfo.com, also known as Breast Augmentation and Implants Information Web Site by Nicole, which I founded in early of 1998.

I paid for all of my own travel and accommodations to be here today, and I will not be reimbursed by anyone for any of my expenses.

I am here on behalf of myself as a happy breast augmentation patient and on behalf of the tens of thousands of women that visit my Web site each month.

I have no financial ties to the implant industry or to any health professional societies. I am not a witness in any lawsuits relating to breast implants.

Thanks to the sponsorship with plastic surgeons who sponsor my Web site, I've been able to allow my Web site to grow to the point where we serve up to over 16 million hits per month and to 160,000 unique visitors each month, all free to the countless women seeking information about breast augmentation.

I launched the Web site about two years ago because I wanted to provide a community for women like myself to share their experiences. The only information I could find on the Internet at the time were surgeon Web sites and society Web sites. They were very helpful, but as a patient I wanted more. I wanted to interact with other women.

Once the site was launched, women from all around the country immediately began to pose questions and answers on my form about breast implants. They wanted to know the issues and the risks.

The amount of ignorance that women came to

the table with -- excuse me? Closer? Sure -- the amount of ignorance that women came to the table with was not surprising. However, the number of women that came was very surprising. I had no idea how many women felt the same way that I did.

I believe that breast augmentation patients now, however, are very different from years ago. Women are much more informed. They are actively seeking this information and taking an active role in their own preoperative education.

I think anyone who has done any research about breast augmentation knows that this surgery, like any other, poses risks. The reasons I am here today is to discuss those risks, as well as the benefits of breast implants.

I am also here to tell you that I believe women today know enough about those risks to decide to choose breast implants and to do so with proper informed consent.

My Web site is currently the number one site on the Internet relating to breast augmentation. I believe that the amount of traffic on my Web site

qualifies me to briefly speak about what women know and feel about saline breast implants.

I've passed out a booklet to each of you that contains some of the stories that women have E-mailed me and posted on my forum. I've received thousands of them and just brought a few today to give you an idea of the type of knowledge that women have and what women have to say about implants and their experiences.

Some of the stories listed on my Web site are in my experiences section, and some I have simply saved in my scrapbooks to remind me on a daily basis how important it is for women to be informed about this procedure. Some of the stories are just happy stories from happy patients, and some are from women who have had complications and still feel the surgery was well worth it.

What these stories also reinforce for me in my own personal sentiment is that despite some of the imperfections that implants may have, like any manmade device, breast implants represent a very positive thing and are able to change for the better

the lives of millions of women.

I would like to read some of those stories to you, and I will try and keep them brief.

This story that I'm about to read is kind of funny, and this person E-mailed me telling me why she felt she wanted to have breast augmentation.

Most women worry about diving into a pool and having their boobs fall out of a bathing suit. For me on a hot, crowded day, I dove into a pool at Caesar's Palace in Las Vegas and had both my curves fall out of my bathing suit. Did you know those things could float?

Well, as I was frantically grasping for the curves, hoping that none of the 500 people sitting by the pool would notice, one thought went through my head. "That is it. I'm getting boobs."

That was just another day in the 32 years of my life where I resembled a 12 year old boy. Has it changed my life? No, but it has changed my self of self. I am no longer self-conscious about my appearance. Okay. Maybe once in a while, like any normal person would be, but it's no longer a daily,

terrible ordeal.

Another woman wrote to me.

I decided to get breast augmentation because I was very out of proportion. I was a 36 AA and had two bris breasts (phonetic) that were almost unbearable for me to look at. I was very self-conscious, even with my own husband.

I spent way too much time comparing myself to other women and never felt adequate as a woman myself.

While the recovery was much more difficult than I expected, I had no complications, and my only regret is that I did not do it sooner. I can actually go through a full day without ever once comparing myself to anyone else or wishing I had something it seems I should have had in the first place.

I feel complete, like a real woman. I am not self-conscious at work or in my personal life, and I love to put on my clothes in the morning knowing that they will fit right.

I did this for me and only me, and I am so very glad I took the time and money to do something

that pleases me so much. I am not ashamed or embarrassed in any way. In fact, I'm proud of myself for being strong enough to admit that I could look at myself, see something I wanted to change and change it.

The next comments that I'm going to read are from a woman with saline implants telling another woman what she would want to tell her if she was considering having this surgery.

If I could tell women anything about my experience with saline implants, I would tell them this is major surgery and not to be taken lightly or with a cavalier attitude. Expect that they won't last a lifetime and that they will eventually need to be replaced. Know that just as natural breasts are seldom perfect, neither are implanted breasts.

If you expect to see improvements rather than perfection, you will most likely be satisfied with your results.

Now, this last story I'm going to read is a favorite of mine because I just think it's hysterical.

Women like myself are constantly asked why we're so vain. Why do we choose vanity? People fix their teeth. They get braces. They get dental implants. No one seems to care.

This woman's response to this was: I was born legally blind in one eye, and it was crossed. I got it straightened a little ten years ago. Nobody ever questioned that or said I was being vain. It was like it was okay for me to fix my eye so other people didn't have to be subjected to its ugliness.

Most people acted like I had purposely offended them with my cockeye and told me I really should have it fixed. I used to literally get beat up in school because of it. Growing up in the Bronx was cruel. Some people would say it was unique or even sexy, and that would make me feel better.

Now, imagine if we were all allowed to walk about topless. People have been insulted if they were forced to look at my breasts because they were so ugly. They would be begging me to fix them and telling me I should get implants. I would have really gotten my butt kicked on a daily basis.

You just can't please them. I really don't care what other people see as right or wrong. This is my life. So I will keep my cockeyes and my implants, and I don't care what anyone else says or thinks.

People really need to learn how to live and let live and stop being so rude and judgmental. It just gets tiresome.

As you can tell from some of the stories that I've read and those that are discussed on my Web site each day, women today are informed about the real risks and the issues surrounding breast implants. Visitors no longer come to my Web site just asking how much will the surgery cost. Instead they now are asking about smooth, round, textured, anatomical, what is rippling, what is the contracture rate, what is the failure rate; they know what the issue are.

Today women overwhelmingly know what they are talking about and know what it is they are choosing, and I'm happy to be a part of that each day.

I have enclosed in your booklet a printout of the index of questions on my form from a typical

day so that you can see the types of questions that women are asking.

In closing, I think that it's vital that I leave you here today with one general theme. It does not and should not matter to you or anyone else why I wanted breast implants or why millions of women want to have breast implants. We are not here to judge whether women should be entitled to want to improve on oneself, and it should not matter if it is for breast cancer reconstruction or simply to augment one's appearance.

What is important is that women should be allowed with informed consent to have this surgery. What you may see as the failure of an implant, such as the potential for rippling, hardening, or the need for replacement, informed women see as acceptable risks in the process where the emotional and psychological benefits outweigh the risks.

Women know the risks about breast implants, and to the extent that they do not, they can be and want to be well informed. If women know the risks and are willing to take the risks, they should

be allowed to do so, and I don't think anyone should take that away from them.

I hope that what I've said here today has been helpful.

Thank you.

CHAIRMAN WHALEN: Are there any questions from the panel?

(No response.)

CHAIRMAN WHALEN: Thank you, Ms. Cummings.

Next, Ms. Lowder from the Toxic Discovery Network.

MS. LOWDER: Good morning. Thank you for this opportunity to speak to each one of you.

I wish my experience had been like the last lady and the letters she read, but mine was not. In 1984, I chose to have saline breast implants put in in Charlotte, North Carolina, after my plastic surgeon told me unequivocally that they would last a lifetime, and I did question. Actually I had not been there for implant surgery. I had been there due to an accident and needed a scar revised, and he brought it up, and consequently I ended up -- it was my choice.

But informed choice I think is one of the key components here.

After I was implanted in 1984, in July of 1984, it didn't take but a few months and I was in the hospital in very serious condition, and that was the beginning of what has been a downward spiral for the last 23 years.

I have been in the hospital for untold surgeries. I have gone through a hysterectomy. The implants were removed in 1984 shortly after the discovered a chest wall tumor just above the left one, and they finally agreed with me that there was a problem. I was leaking a grayish-black matter, and then the doctor got in there, he discovered that I had fungus and large black particulate matter.

Now, I'm not saying that every implant has this kind of a problem. I don't know, but I do know and I can tell you that I experienced it, and what ensued, what happened after that was a nightmare.

I ended up with a total hysterectomy the same day that they removed the implants. They discovered that I was filled with tumors that I had

not had before.

I need to backtrack a little bit right now. I had been an Olympic contender ice skater. I was a dancer, ballerina. I was an equestrian. I played the piano. I was a very happily married woman with two very young boys, very active, healthy boys. I had whatever in this world wants. I had a loving home and a family.

That surgery on December 5th, 1984, where they removed the implants and the hysterectomy, was just obviously just prior to Christmas. On Christmas morning, the two boys and I were waiting at the Christmas tree for my husband to come downstairs, and he came down with one bag in his hand, and he said with regret that he was really sorry, but he just didn't want the responsibility anymore. He didn't want to be married to somebody who was so sick. So he left.

I have gone through countless surgeries. It's too many to even go through. I, in fact, go home from here to have a couple more tumors removed from my abdominal area and for a third time a cell tumor out

of my hand.

The seizures, the MS-like condition can only be handled where morphine -- I take 60 milligram os morphine daily just to get through. Fortunately my boys are now grown, and they've been educated, and they're on their own, and I thank God for that because I don't think I could go through it again.

My experience was not what you hear some of these women sharing about, oh, the wonderful side of implants, and maybe there is a wonderful side. I can't address that. I didn't experience it, and the women I talked to on almost a daily basis have not experienced it.

I was not informed. I don't know what it would take to have doctors explain what the real problems can possibly be or what people can expect from implants, but what I do know is that it is an elective surgery, and until we have an assurance that people like myself are not going to go in expecting nothing but good things and come out with a total disaster, maybe it is chemical sensitivity. I don't know, but I think we need more answers before we can

just unequivocally, indiscriminately open the doors and say anybody that wants an implant, come get it because there are too many that are unsuspecting like I was.

Today I am in total financial ruin. I lost my home. I had to close my business that I loved. Excuse me.

I was a commercial designer. Not too many people you talk to can honestly say they love what they do, and I did. I loved every moment of it, but the day that I was -- pardon me -- driving from Sandy Springs in Georgia to Cumming, Georgia to meet with a builder on a major highway, I had a seizure. The neurologist and my other doctors had been trying to convince me that it was time to back away from my career.

Well, that day I had no choice. When I said that I thank God that my boys are grown. They were robbed. They were robbed of a mom that was a happy, healthy, well adjusted person. Instead what they have to remember is a mom not knowing whether or not when they came home from school I was going to be

in the hospital, whether I was going to be in bed or whether I would be able to cook dinner for them that night.

When I say this has been a nightmare, it really has, and I don't think you people sitting up here want to open that can of worms or continue to allow it to be open until there is some recognition of what has and what is going on.

There are too many people. I hear the same stories day after day after day. I have what is typically known as ANDS. It's like MS, along with a whole host of other things, and they're too long to even go into.

I wrote them all down, and I thought that sounds like a laundry list. There's no point in getting up here and reading off to you what's wrong with me today. I hate it. That much I can tell you.

I came to know a woman by the name of Kathy Keithley Johnston with Toxic Discovery Network going on three years ago now. She had started from pure love in her heart a nonprofit organization to help women who were and had gone through situations

like I've had, and she's been there, and she has continued to be there for me.

As I close, I want to read a statement from Kathy who has had to close the doors of TDN, but before I do, one other thing I want to mention to you. I purposefully have not named the manufacturer of my particular implants. The reason you don't hear as many of these stories as you could is because six years ago now the manufacturer that was involved with me decided to pay me while I was still involved in the global settlement, and my part in that was I had to sign an agreement, a contract not to disclose and not to repeat what was in the contract or anything about my story. I had to remain silent. I could not tell anybody the nightmare that I had gone through or that this manufacturer was paying me $3,300 a month, and they did for four years.

They stopped paying me in November two years ago now. My father, my brother, and my oldest son are helping me stay afloat. That's a hell of a note for somebody who was as proud as I've always been.

I'm sharing that story with you because, about the manufacturer, for one reason. I question why I was being paid to be quiet. I had saline implants. I had the same saline implants that they've had a number of problems with, a lot of problems with.

I'm not going to be their conscience. The story will come out, but I'm not here today to try to run them into the ground. I'm here to talk to you, the FDA, about a product that I don't think is safe.

I just want to close with a comment from Kathy Johnston who has selflessly given of her time, their money, and her love. Kathy is an R.N. and president and Medical Director of Toxic Discovery Network, and she wanted me to read this quote, and her comment was, "I want it read loud and clear."

The right to choose is meaningless without the right to know, and I think that's pretty poignant.

And with that I thank you for giving me the time.

CHAIRMAN WHALEN: Would you entertain a question, Ms. Lowder?

DR. BURKHARDT: Hi. I have two questions.

The first is that you referred to the global settlement in relation to your saline implants. It was my understanding that the global settlement had to do with the silicone gel implants, but you had saline implants, and you were part of the global settlement?

MS. LOWDER: That is correct.

DR. BURKHARDT: The second question is that you've obviously had an enormous amount of difficulty for which I think any of us must feel great empathy and sympathy, but it was not really clear in your presentation to me why you related that to your implants.

MS. LOWDER: Because it has been directly tied together. I have, and I apologize that I didn't tie it together.

I have silicone -- even though I had saline implants, I have silicone in my lymphatic system, in my brain, in every tumor that has been removed that they have checked since 1994. I have silicone, and my first question was: well, how can I have silicone when I had saline implants?

The answer to that is the outer casing is

silicone.

DR. BURKHARDT: Thank you very much.

MS. LOWDER: Thank you.

CHAIRMAN WHALEN: The next speaker is Ms. Lynda Roth from the Coalition of Silicone Survivors, and I would remind each of the speakers to please answer for us the questions at the beginning of their presentation that have been posed by the FDA.

MS. ROTH: Thank you.

I paid my own way to this meeting. I came of my own volition, and sadly I will not be reimbursed.

I have no financial ties to industry or any group or individual in the health professions. I am included as a claimant in the current Dow Corning bankruptcy settlement. I did receive a settlement from Mentor for a whole $1,519. That was from almost dying.

I derive no income from anything related to breast implants. In fact, it has cost me many thousands of dollars to help others with the situation.

Ladies and gentlemen on the panel, I'm a social worker with MSW and the leader of a support network for women with breast implants. I'm here today to represent the many women who are unable to come.

There are numerous reasons for their absence. Among them, the inability to afford a trip; illness; and their feelings that they could not speak eloquently enough to get their points across.

Many are embarrassed that they made this medical decision only to become ill and become a burden to their families and friends. They hide their shame.

Some fear the legal repercussions of being public while legality still exists of these devices. I'm here today to tell you my experiences with these women and with saline filled breast implants.

Our network has existed since 1990 and has about 5,500 members. About 25 percent of those women who have had only saline filled silicone implants. A few of these women do not have problems, but they are concerned. The vast majority have medical problems

caused by their implants.

As saline filled implants become more popular, the percentage of calls coming from women with these breast implants has mushroomed. In the last three years, our calls have consisted of more and more saline implantees, nearing 50 percent today.

Our network provides information free of charge throughout the world to those who cannot afford to pay for it, and we do provide a newsletter that some people pay for.

We are incorporated as a 501(c)(3) nonprofit organization.

Silicone is not biologically inert. It may be chemically inert. The silicone in a shell contains many chemicals which react when placed in a biological setting. Some of these chemicals are known to be harmful to the body.

I am sure you have a list of all the contents of the shells of these devices. I urge you to read about the harmful effects of each. They are not inert devices.

Biochemical reactions can and do occur.

When implants are removed, often scar tissue remains. Some of the harmful chemicals that slough off the shell will remain in the chest, causing further reactions.

Foreign bodies are known to cause reactions. The calcium deposits that form in scar tissue resemble cancerous tissues on mammograms. Screening for cancer is much more difficult with any implant.

Women who have had cancer are known to have a suppressed immune system. I am one such woman, and although at the time the implant seemed like a great idea, it was probably the biggest mistake of my life. It almost cost my life.

Women who have suppressed immune systems should not be exposed to products that are known immune system suppressants. The manufacturers of saline that goes into these implants are on record as stating their solution is not meant for long term implantation into the human body. It is a dated solution, and one that cannot be guaranteed to remain sterile.

Generally the date is less than a year from the time of the implantation. Sterility is only as good as the conditions of the operating room and the cleanliness of the medical persons involved.

In addition, sterility is never 100 percent, even with the modern ways we have to sterilize medical devices.

Implants are microporous. They exchange fluid with the body. Anything in the implants can get into the body and vice versa.

We all have bacteria and fungi in our bodies. This leads to the incubation of nightmarish microbes that cause serious damage.

Saline implants can and do rupture, often. Besides the risk of the original surgery, women are exposed to repeated surgeries for years to come. The FDA reportedly has over 25,000 claims of injury from these saline filled devices. We have heard that our government is here to protect us. What have they done about these claims?

Some of the most common problems reported to us are deflation of the implant, often within a few

weeks after surgery; hard, painful breasts; shifting of the implant so that it has to be surgically moved back where it belongs; body aches, joint pains; loss of energy; unexplained rashes often on the chest and neck; burning, twitching and weakness of muscles; and short-term memory loss.

Many women report significant hair loss all over their bodies, including eyebrows and eyelashes, and this problem usually reverses with implant removal.

Women also report skin and nipple necrosis. Testing often reveals antibodies to silicone.

I would like to specifically address the studies that the manufacturers have conducted, the so-called five year studies. First, I want to mention the lack of informed consent.

Product label inserts are not often given to the women. Women often have these implants placed without hearing a word about the possible problems. They report being given papers to sign when they have been prepped for surgery and have been given a

sedative. They report being given papers to sign after the surgery before they are fully recovered from anesthesia.

I have heard from more than a dozen symptomatic women in the last three years who have never been contacted by their plastic surgeon after implantation with saline implants, despite the fact that they were told they were in a study about the safety of these devices.

These women's symptoms remain unreported. If I had heard from this many and other group leaders have heard from at least this many, how many others remain unreported?

These women are all part of a study being done by McGhan or Mentor. The plastic surgeons that insert the implants are collecting the data. This greatly reduces or eliminates any scientific validity of the study.

Another problem is that a study that only goes on for five years can hardly define risks that may take 20 to 30 years to discover, as in the case of asbestos. We know for a certainly that women with

silicone implants often do not show symptoms for at least six to eight years. For some it is 15 years or more.

What possible value can a biased study, one in which not all the plastic surgeons follow up with patients and that only goes for five years, have? This certainly calls into question the accuracy of the data of these studies that you will hear at this PMA meeting.

These saline filled silicone implant studies need to be followed by unbiased researchers for at least 20 years before we can know what damage they will do to many of the recipients.

I have heard doctors joking about these studies, stating that they are a study in name only. I seriously doubt that any of these doctors who make money from placing implants are going to come here and admit that these studies are not scientifically valid.

A survey of all women implanted should be done to find out how many had problems and how many have reported these to their plastic surgeons. This should not be done by manufacturers of implants or the

plastic surgeons. The FDA should closely monitor these studies and check the accuracy of the information regarding these.

Women call our network with illnesses after a few years after implantation stating that they have never heard from their plastic surgeons. When they do finally call their surgeon complaining of symptoms, they are told that these symptoms could not possibly be from the implants.

I have heard from one of these women again recently, and after four years she had not once heard from her California plastic surgeon, despite the fact that she was told she was enrolled in a study. She finally called his office to report problems and was told that her problems were not of the type implants cause.

I'm including the E-mail of one woman who contacted me less than three weeks ago. She had her saline implants for four months and was already symptomatic. When she contacted her plastic surgeon, he told her it was not due to her implants.

She has persisted, and he has removed

them, but with great reluctance. I do not believe this is an uncommon problem. From the reports I get from women and other support group leaders, this is an extremely common situation.

Those of us who speak out are called fanatical, hysterical women. I am a serious, practical, intelligent, and educated woman. I am dedicated to informing people on this issue.

If this meeting is not a serious effort to evaluate the safety of implants, but instead a rubber stamp to please the manufacturers by approving their products, then I ask that you make absolutely certain that all women are at least a week before the surgery given the important information about side effects. They need to be informed of the wealth of information available. They need to be given this without bias or comments by the physician.

Often concerns are just waved away with a sweep of the hand and a statement that "we don't have any problems with this." That's exactly what happened to me.

My group members report this same

paternalistic response from their plastic surgeons. Maryland is a good example of informed consent law. The state has an excellent policy of informed consent regarding implants, but unfortunately the doctors do not comply.

There's an increasing problem with younger and younger women desiring on getting breast implants. The age range is from 13 to 17 years of age. Although some few plastic surgeons refuse to implant women so young, most can and do take these young women, children, as patients. They are not yet old enough to understand the lifetime of surgeries and problems that may occur, yet they are having implants placed in their body.

Ethically and morally these women should not be candidates for surgery. Their parents need to be truly informed of all the problems. Often these young women's bodies are not finished with development. Yet they're being exposed to surgeries.

You will hear about the social aspects, the self-esteem issues, the self-worth issues, and the feel good issues, "about myself now" reports here

today. Many, many of the results are just the opposite.

The emotional pains are tremendously high. Women commit suicide to escape the pain. Increasing numbers of women are being granted disability. The taxpayers are paying for this. I know women who had saline implants in the '70s, and they are on disability. I'm grateful often that I'm not in their shoes.

The last point is that women have to sign away their rights to ever sue the manufacturers of these devices now. They have to sign a waiver saying they will never sue if they get implants. If they are so safe, why are we having to sign away our rights to ever sue?

The manufacturers know these devices are not safety.

In conclusion, I thank the panel for your time, and hope that you will make the decision to require more study on saline implants before any approval so that women of this country and, indeed, the world will benefit from this hearing.

Thank you.

CHAIRMAN WHALEN: Would you entertain a question?

MS. ROTH: Sure.

CHAIRMAN WHALEN: Dr. Dubler.

MS. DUBLER: Thank you for your testimony.

You said that you were dedicated to informing women, and I wonder what sorts of information do you think they should have. Should they have the data on the package insert? Should they have the raw data from some of the studies that have been conducted?

How would you go about informing them?

MS. ROTH: Maryland has an excellent brochure that has quite a number of pages. I would ask that you look into that and find out exactly what they have done, but in informed consent, information is no better than the doctor who is giving it out, and regretfully, most doctors do not give informed consent to their patients.

Now, the FDA has had currently understood risks of saline filled breast prostheses, which I have

here, for years. There's a thing on the back that says "signature," "date," "witness." These are not being filled out. These doctors are not giving these to the patients, and if they do give them anything, they wave it away and say, "Oh, this is just a formality. We don't have any problems with these," which is exactly what happened to me.

MS. DUBLER: So are you suggesting that the materials be given out, that are given out by physicians, be composed by other people?

MS. ROTH: Oh, absolutely, and that the plastic surgeons be informed that they are not to discount this information because patients truly have a right to informed consent.

And I do have a picture here that was sent to me by one woman. She wants it back, of a saline breast implant that was removed from her body. So I would like to give you this information and share this picture.

CHAIRMAN WHALEN: The next speaker is Ms. Eileen Swanson from Survivors of Salines.

MS. SWANSON: Good morning. My name is

Eileen Swanson, and I am here to tell you of my experience with saline implants and the experiences of that of my support group members, Survivors of Salines.

To answer your questions, because I am on disability and have low income, I accepted the offers of small donations for this trip from several other breast implant survivors. I also received an honorarium to participate in the workshop yesterday from the National Center of Policy Research for Women and Families, a nonprofit research center.

I have no financial ties with industry or health professional societies. I'm a claimant in the Dow Corning bankruptcy, and the answer to four is I derive no income from surgical procedures using breast implants or from treating patients with complaints they believe are related to breast implants.

My Web site and support group, Survivors of Salines, is entirely supported by me and the information is provided free of charge.

I was implanted with Mentor leaf valve (phonetic), smooth shelled, saline breast implants in

July of 1989 for reconstruction following Stage 2 breast cancer on the right and prophylaxis on the left. Other than my cancer diagnosis, I was healthy and active.

The right implant deflated in the recovery room before I even woke up. It went straight downhill from there.

Another surgery followed, a saline only tissue expander a few months later, then a new set of Mentor saline textured surface implants two months after that.

In the following months I suffered from local complications: infection on both sides, swollen lymph node, pain, redness and swelling on both sides, rash and skin tags on my chest and under arms, burning chest pain which persists to this day, Baker III contractures, and a cluster of lumps on the left mound which mammography indicated was a crease in the implant. The lumps were later biopsied and found to be fibrocystic changes in my tissue.

Systemic symptoms began suddenly the third week of April 1990 and included widespread, constant

pain, morning stiffness, frequent cramps, diarrhea, nausea and vomiting, ceca symptoms, severe headaches, bladder pain, frequency and incontinence, extreme neck pain attacks which leave me bedridden, abnormal fatigue, difficulty in concentrating and short term memory loss, chemical sensitivity, and a sleep disorder which I was told was called fragmented sleep.

I was explanted in May of 1991. I had a brief reprieve, but then my condition deteriorated. The scar tissue capsules imbedded with microscopic fragments of silicone were left in my chest underneath the muscle. Doctors tell me that surgery to remove them now would likely mean scraping my ribs and possibly doing more harm than good.

In September of '93, four years after implantation, my condition worsened. I developed numbness, paraesthesias, and burning pain in my legs and feet, arms and hands and face. These caused me to stumble and fall easily, shuffle my feet and drop things, have difficulty breathing, difficulty swallowing, sudden onset inability to speak, disorientation and dizziness, and balance

difficulties.

You can imagine with all of these symptoms I've named so far what it's like to live on a daily basis.

I lost my photography business in 1994 because I could not hold my camera, move the props or backdrops, or even remember the technical details of my trade.

I lost my marriage, my health insurance, my home, and I live in the attic bedroom in my mother's home. I'm on SSI and Medicaid now. I used to be an active Army wife, full-time mother of three, a community volunteer. I enjoyed cross-country skiing, bicycling, hiking, and bicycling, in addition to working full time.

Now I'm lucky if I can walk around the corner to church on a really good day.

Board certified doctors have diagnosed fibromyalgia, with all of the symptoms that are defined by the American College of Rheumatology criteria.

My current neurologist says that despite

normal EMG, she feels I clearly have a neurological problem in my legs, at least in my legs.

My current rheumatologist states that he believes I have more than fibromyalgia due to the abnormal blood work which he says indicates inflammation, such as elevated ANA, C reactive protein, retic count and CPK.

From the time I was 39 years old, nearly ten years ago, my life has been an agonizing struggle to do the everyday things most people take for granted. I have adverse reactions to nearly all medications we've tried, even herbs and homeopathic remedies and even food. So treatment and pain management remains an extreme challenge.

In 1998, I founded Survivors of Salines, which is an Internet saline implant support group, because I wanted to educate women about the risks. I have heard my story repeated in countless women who have written to me who have had saline implants. They have similar symptoms and similar difficulties in obtaining effective medical treatment.

Women like me who have had only saline

implants, never gel, tell me they're experiencing deflations, rippling of the implant shell, infection, contractures, multiple surgeries, joint pain, fatigue, hair loss, irritable bowel syndrome, bladder pain, tremors, memory loss, chest pain, sleep disorders, fibromyalgia, lupus, neuropathy, scleroderma, and allergic reaction to silicone.

I'm sorry.

Women who have replaced silicone gel implants with saline implants report that their conditions worsened after receiving the saline, often having violent reactions such as intense inflammatory response in the breast, along with the other symptoms they have already had.

Most of these women tell me that their symptoms are debilitating, and many are on disability. Women seeking to be implanted often tell me that their doctors did not even advise them of the risk of local complications. They are frequently not aware that the shell is silicone, much less that it can shed microscopic fragments, and they are always shocked when I tell them that sterile saline has a shelf life

after which time it has been shown to support microbial growth.

I am requesting that the pre-market approval applications for saline filled silicone breast implants be denied because the following have not been accomplished: standardized testing for allergy to silicone for all saline implant patients.

Salastic (phonetic) allergy was documented in 11 percent of patients in a study of endolymphatic subarachnoid shunt failures in 1998. According to the American Society of Plastic Surgeons, the silicone shell of the saline implants parallels the material that makes up other medical devices.

Second, a national registry of saline implanted women by a government agency, information from which is made available to saline implant patients, to include numbers of women implanted, symptoms experienced, and treatments available.

The plastic surgeon is often the sole source of information for a prospective implantee and may have little incentive to advise breast implant patients of possible complications since they earn an

average of $3,000 from an augmentation or a reconstructive procedure.

Instead of the current climate of denial, there should be early detection of breast implant related symptoms, whatever they might be.

And third, studies and tests involving women who have saline implants and are sick. This is not a novel concept. It happens all the time when a new illness becomes known, such as Legionnaire's Disease in 1976. The CDC intervened and discovered a new bacteria.

In our case, it would seem to be common sense to test not only for reaction to the silicone shell, but also for bacteria and fungi which have been shown to grow and reproduce in no longer sterile saline, even though it is the FDA's position that saline filled implants are less risky because they release only salt water when they rupture, and not silicone gel.

I am asking you to protect future generations of women in a way that I was not. It never occurred to me that my doctor would place an

object in my body that was not approved for use in the human body.

There is no proof that saline breast implants are safe, and isn't that what should have happened before they were ever placed in women's bodies?

Breast implants are not life saving, nor do they restore function in any way. Please do not allow women to continue being used as guinea pigs.

Thank you.

CHAIRMAN WHALEN: Thank you.

Our next speaker, we're going to go slightly out of order and go back to an individual consumer. So this will be a five minute address maximally to us rather than a ten minute address. And this will be Ms. Lisa LaCivita.

MS. LaCIVITA: Hi. Thank you.

I'm sorry I couldn't make it at my predetermined time. I'll be very brief.

My name is Lisa LaCivita, and I am a woman that chose to have breast augmentation, and in coming here I had none of my travel or accommodations paid

for. I don't have any financial ties to the industry. I'm not party or witness to any lawsuits involving implants.

However, I am an anesthesia provider, and I do derive income from surgical procedures involving breast implantation. I think that you should know that.

But I'm here as a consumer advocate for a women's choice to have breast implantation, and I really believe that whether it's for reasons of vanity or self-esteem or to correct gross disfigurement that results from necessary surgical procedures, that it should be a woman's choice to have breast implantation.

It's the responsibility of the FDA to determine the safety of the products that we are implanted with and the responsibility of the patient's surgeons to discuss the risks and the benefits of the surgical procedure.

Then it's the responsibility of the patient to make an informed choice and to give informed consent to proceed.

I'm a nurse anesthetist that works in a cosmetic surgery center, and for the last ten years we've done about 250 cases a year, about 90 of which are breast augmentations with saline implants. During that time, we have not had any difficulty with patients, and the data that you have is part -- we participated in the data that was contributed.

But we haven't had any patients come back and ask that their implants be removed. The most common risk or adverse event that we have seen has been mild capsular contracture, and even then patients may come back and have their implants removed, have a capsulectomy, and then have the implants put back in, but none of them have chosen to have them removed and to remain so.

So in conclusion, I'm just here to urge that you not take away a woman's right to make informed choices when considering breast implantation.

Thank you very much.

CHAIRMAN WHALEN: Thank you.

Returning then to the consumer group list, so back to ten minute presentations maximally, we have

next Ms. Susan Sherr from the National Coalition of Cancer Survivors.

MS. SHERR: Good morning. In response to all four of your questions, the answer is no.

My name is Susan Sherr, and I thank you for this opportunity to speak to you, to this committee this morning.

I'm speaking today as a representative of the National Coalition for Cancer Survivorship, and I will correct that in the record, NCCS. It is the only patient led organization advocating on behalf of survivors of all types of cancer.

But I also am speaking today as a 22 year breast cancer survivor and one who has had personal experience with both reconstructive surgery and with breast implants.

I have previously testified before the FDA when silicone implants were being reviewed, and in 1998, on behalf of the Cancer Leadership Council before the IOM Committee reviewing the safety of silicone implants.

I mention this because NCCS' position and

that of most of the major cancer organizations has essentially remained the same since 1991, and that is that evidence based science be the determinant in your reviews, questions, deliberations, and findings.

There will be several organizations and individuals testifying about the importance of options particularly for breast cancer survivors and on the topics of quality of life, mammography screening, and an informed consent. So I will not address these issues in my remarks.

Unfortunately, the silicone implant issue is one that has been contentious and litigious, and one that has pitted woman against woman, created a media frenzy that has led to fear and misinformation in the general public. We do not want to see this replicated with saline implants.

As an organization representing survivors of all types of cancer, all ages and both sexes, it is especially important to us that the FDA factor in the ramifications of faulty or non-science based decision making be it for a drug, a biologic, or a medical device.

By this I mean the implications for manufacturers of other drugs, biologics or devices leading to the potential loss or reduced development of new products, thus affecting patients and their treatment options.

It should also be understood that although this hearing is about saline implants, and NCCS is primarily concerned with the outcome for cancer survivors, we are also concerned that the process by which a decision is reached be thorough, thoughtful, balanced, and not subject to hype, emotion, or possible bad publicity that the FDA might receive.

Unlike the environment when silicone gel PMAs were being considered, there is considerable information and data available about the safety and efficacy of saline filled implants. In studies conducted throughout Europe, China, and the United States, contracture, rupture, under inflation, over inflation, texture, microbial growth, and even noise following surgery have been reviewed.

We are appreciative of the role of the FDA in protecting all citizens of the United States from

unsafe and harmful products, but we do not need the FDA to take a paternalistic position. Women who are well informed are perfectly capable of making good decisions, and women who have already dealt with a diagnosis of breast cancer may be inclined to accept more risk than the average person. They should have this right if nothing dangerous or unexpected is presented in the PMA data.

It is also important that the FDA include the patient experience as a body of evidence when making its evaluation, both pro and con, and that the established, respected, and reasonable patient-consumer advocacy community be more involved in the process.

Thank you.

CHAIRMAN WHALEN: Thank you.

Next is Ms. Sybil Niden Goldrich of the Command Trust Network.

MS. GOLDRICH: Good morning. Command Trust Network has paid my way here. I do not receive any grants from any industry people. I am -- I have been appointed by the federal district court to

represent women on certain panels in MDL 926. I am the consumer representative to the Tort Claimants Committee on the Dow Corning bankruptcy.

I get no money from performing surgical procedures.

I'm grateful for this opportunity because we're at a very critical juncture in the long unresolved debate over breast implants, and I'm going to repeat today some of the very same remarks I made to this panel 12 years ago when I first spoke.

Unfortunately, the issues that I raise today must again be addressed.

I thought to myself, gee, I've last longer than a lot of implants.

(Laughter.)

MS. GOLDRICH: The FDA continues to be caught in a situation where virtually all classes of implanted medical devices, including breast implants are sold to millions of Americans without full and open analysis of the risks versus the benefits.

Last year 130,000 saline filled implants were sold in the United States. I've been a consumer

advocate for more than a decade and have had the occasion to speak to many women with saline implants. Believe me when I say that a large percentage of them are surprised and even shocked to learn that the safety of saline implants has never been formally approved by the FDA.

They are also keenly disappointed to learn that the manufacturers were under no obligation to begin collecting safety data until 1993, 20 years after saline implants were first marketed. Much of the industry data that will be presented to this panel, therefore, will be of very limited value. It is not possible to evaluate the long term risks of saline implants when the data is only on a short term basis.

Moreover, the two findings from the PMA data that were released prior to this conference are disturbing in their face. In the first instance, I refer to a recently published comment from Dr. Bruce Cunningham, who was the lead researcher on the PMA studies. He has reported that the failure rate for saline implants was five percent per year. At that

rate, after five years, one in every four saline implants will have failed. After ten, half will have failed.

This was on the WebTV article.

A woman who has double implants is essentially guaranteed to have one of them fail within ten years. Of course, the failure rate between the five year mark and the ten year mark may be worse. We don't know. We don't know because there's no data available from that time period.

Secondly, I refer to an industry study that was cited in last years Institute of Medicine report. Based on an observational survey of 2,855 women who received saline implants during 1995 and 1996 from McGhan Medical Corporation, it appears that women with saline implants must return to the hospital at a much more alarming rate than women with silicone implants.

With silicone implants, one in four women need additional surgeries within the first five years, according to the Mayo Clinic. According to the McGhan data, however, one in three breast cancer survivors

had to return to the operating room within the first 12 months with all of the inevitable risks and expenses involved in those procedures.

The McGhan study divided women into two categories: post-mastectomy reconstruction and augmentation. Of the cancer survivors, 35.9 percent suffered infections, deflation, contracture, or other problems that necessitated removal of their implants.

For augmentation patients, the rate for the same set of problems was 18.9 percent. Although it seems that one in four saline women need new surgery within the first five years after receiving -- altogether it seems that one in four will need new surgery within the first five years after receiving implants. In other words, the rate for saline implant patients is approximately five times higher than for silicone implants.

But we can't really know this for sure, again, because it's only a one year study. I urge the panel to make every effort to consult with medical professionals and other knowledgeable experts to obtain all of the available evidence before making a

final decision.

Bioethical concerns are very important. Because breast implants are under the category of a cosmetic rather than a life saving device, most women assume that the risks are minimal or nonexistent. They had better be prepared to accept a higher risk in the case of a brain shunt or a heart valve, but not for breast enhancement.

Therefore, I recommend that this panel, the panel members, attempt to elicit the answers to the following questions:

One, what is the threshold of safety that must be achieved before cosmetic devices are made available for general marketing?

Two, how does the safety standard for cosmetic devices differ from the standard for life saving devices?

Parenthetically I might add: has the FDA ever approved a medical device that is not a life saving device when it has as high a failure rate as breast implants?

Also, how long should the surveillance

period be to enable scientists to measure epidemiological results?

My medical concerns. Slick advertising, most women today are misled into believing that breast implants have been proven safe. It is important that you make the following determinations.

What is the rate at which women with saline implants experience capsular contracture, infections, loss of nipple sensation, skin numbness, skin rashes, or bacterial contamination?

What is the rate at which saline implants deflate or rupture?

What is the time period for these rates?

What is the rate at which saline implants interfere with mammographic tests for breast cancer?

Informed consent. Women who decide to undergo implant surgery only after a limited knowledge of the risks, later many of them say, "If I'd only known, I would have said no," but then it's too late. Most patients are not unduly upset if unpleasant information is provided at the outset.

What upsets them far more is when any

level of truth is withheld and when only half truths are provided. I urge that the panel press hard to resolve the following.

What level of information is necessary to permit consumers to make an informed consent decision about breast implants?

How will women be notified in detail about potential risks, complications, and the longevity of devices prior to implantation?

Will the package labeling include specific data about the rates and time periods of all medical complications?

Will photographic examples of medical complications be made available to women to enable them to visualize the potential risks?

Will the package inserts be provided in duplicate so one can be kept in the surgeon's files and the other be given to the patient?

How will women be informed that their implants may interfere with mammograms and self-exams for breast cancer?

The last thing I want to approach are long

term studies. The Institute of Medicine recommended last year that a standardized system, some type of registry be set up to help collect even more extensive information about the frequency, causes, management of medical complications of breast implants.

I asked for that in 1988. The following questions fall fully on the FDA to address.

Number one, should the FDA establish a monitoring system by which the implanted devices are tracked and retrieved upon removal for further study?

Should they be a chain of custody set of documents?

Should breast implants be registered in the national registry by model number and serial number?

Should consumers be informed of the model number and serial number of their individual implants?

Should they be issued a permanent wallet size card marked with all permanent information about their implants? How does that protect their personal privacy?

If a certain model of implant is deemed

defective, what's your recall procedure? Who's going to pay for the cost of the recall?

Adequate information was not available to me when I got my breast implants after breast cancer. I've had persistent health problems after my surgery. I've had two implant replacement operations.

The article I wrote for Ms. magazine in 1988 brought widespread public attention to this issue and ultimately led the FDA to the moratorium for the devices in 1992. What I said then and what I will reiterate now: the patient's interest is the only valid interest in this equation and only it must be served. A product that is merely not unsafe should not be placed in the general marketplace. The American public expects and deserves that the FDA approve only those products that can truly be called safe.

Please don't fall off that very fine line that separates the two.

Thank you.

CHAIRMAN WHALEN: Thank you.

Question? Ms. Brinkman.

MS. BRINKMAN: Yes. Ms. Goldrich, you made some good points. I can't write fast enough. So --

MS. GOLDRICH: I spoke too fast.

MS. BRINKMAN: -- is there a possibility that some of the lists of points that you would like the FDA to consider, such as labeling and other issues that you made, just a brief list of what those are?

MS. GOLDRICH: I will be very happy to supply them to the panel and whatever group the panel chooses to write these documents. I did serve on an early advisory committee on writing the informed consent documents, but that committee was manned by manufacturers and plastic surgeons, and at the very end of that committee process, it was decided that the support groups were not even to be listed as an information source.

I hope that we have gone well beyond that in the last 12 years and that we can get some really solid answers to my questions. I'll supply them to you.

CHAIRMAN WHALEN: Dr. Burkhardt.

DR. BURKHARDT: Ms. Goldrich, I was listening as carefully as I could, but I think I missed some statistics that you reported from the Institute of Medicine Report.

MS. GOLDRICH: Yes. I have to go back to those.

DR. BURKHARDT: Did you say that 19 percent of patients who had augmentation with saline implants had their implants removed within one year?

MS. GOLDRICH: Yes, I did. I think I did say that.

DR. BURKHARDT: And that's in the report?

MS. GOLDRICH: Yeah, it is.

DR. BURKHARDT: Thank you.

CHAIRMAN WHALEN: Any other questions? Yes, I'm sorry.

MS. DUBLER: You mentioned at one point the package insert.

MS. GOLDRICH: Yes.

MS. DUBLER: And I wonder, again, if you're suggesting that the package insert is appropriate to go to all patients. The struggle in

informed consent construction has been to alert the consumer, the patient, to the material risks and those on which the patient should focus.

Do you think that the package insert will help that process or perhaps hinder it?

MS. GOLDRICH: I find it interesting that for many years I have asked for the manufacturers to package the product in such a way that the package insert is on the outside of the box rather than on the inside of the box.

The box is opened in the operating room. It doesn't even do the doctor any good there. I do believe that the package insert should be supplied to a patient.

When you buy a bottle of medicine in the pharmacy, they give you this big, fat thing stuck to the side. It's the package insert. There's no reason we shouldn't have it, and we should also have supportive documents to explain that package insert, but to keep it from somebody makes that person think that you're keeping a secret.

There can be no secrets about this

product. The package insert should be made in duplicate. The doctor should be required to write that he has read this new package insert. They change them all the time. Whenever they lose a lawsuit they change the -- they up the ante and change the package insert, and the patient should be given that package insert.

Let her go home and read it at three o'clock in the morning when the questions some. What am I doing? Should I do this? Is this healthy for me? Am I safe?

I think it's only reasonable. The more information you get, the better, and I don't think in the long run a lot makes it more confusing. I think what happens is you see certain issues repeated over and over again, and then they're repeated, they hit home. People understand.

Anything else?

CHAIRMAN WHALEN: Thank you.

MS. GOLDRICH: Thank you.

CHAIRMAN WHALEN: Next is Ms. Cynthia Pearson from the National Women's Health Network.

MS. PEARSON: I'm Cynthia Pearson. I'm the Executive Director of the National Women's Health Network.

The network is an independent member supported organization dedicated to using a science based analysis to safeguard women's health rights and interests.

We accept no money from pharmaceutical companies, medical device manufacturers, or trial lawyers.

And in answer to the four questions, we have no travel expenses. We have no ties with anyone in industry or professional societies. We're not involved in any lawsuits and derive no income from clinical services.

Some of the panel members and FDA staff remember that the FDA has been actively involved as a voice for women consumers throughout the long history of FDA's consideration of the regulatory status of breast implants. For nearly two decades we have advocated for the agency to first classify these devices as requiring study, and then to require the

manufacturers to provide data demonstrating the safety of these devices.

We're pleased that the day has finally arrived when this panel is meeting to evaluate data that have been collected on saline filled breast implants and make a determination about their safety.

We're also pleased to have the opportunity to speak here. Unfortunately we've been forced to prepare this statement in something that's a vacuum, as you see that most of the public speakers are speaking in advance of the data presentation.

Because of this we'll make our remarks in a way that just give our general impression, but hope to have some opportunity to participate tomorrow after data have been presented.

We believe, based on what we know as of this morning, that saline filled implants have not yet been tested in an adequate way to demonstrate that they are safe for anyone. There's no long term data available showing what happens to women with implants after five to ten years.

This deficiency is particularly

frustrating in light of the fact that women have been using these devices for more than 30 years. This use has been based on their belief that the products wouldn't be available if they weren't known to be safe.

The women are out there, and we know as well as you do the deficiencies of retrospective studies, but they were a potential source of collecting data on the long term effect, the effects of long term sue of implants, and the fact that this opportunity has been ignored makes us question whether for some reason the manufacturers don't want the answer to that question.

But the women want the answer to that question, especially because of what we are beginning to know in a very scientifically valid way about the short term experience and safety record of the implants. We've heard some reports this morning of PMA information that have been discussed publicly that don't sound so wonderful, you know, a steady, constant breakage rate, a reoperation rate.

These are serious and painful health

problems, even setting aside the question of whether there are larger systemic effects.

These complications are not contested. Everyone on both sides of the issues agrees, acknowledges that they occur, although the data that establish the frequency with which they occur are only beginning to be made public.

Similarly, in addition to the hardening of breasts and infections, the breakage rate is a common problem; the need to undergo another surgery. This means that women, if the average age of implants is still in the early 30s, although it may be dropping because of the growing popularity of implants inserted when women are teenagers. Women might require reoperations every five years. I'm just guessing, or every ten years for the rest of their life.

This is a serious consideration that individual women must weigh and face, but we believe that the panel has to also weigh and face as to whether a product with that kind of regular failure rate can be considered to be approved for certain groups of people.

We are specifically concerned because of our long history of work on breast cancer issues and with the new in the '90s wave of breast cancer specific survivor groups about the affect of implants on women who receive them following mastectomy.

It appears, based on what we know this morning, that relatively few of the women studied for the somewhat short term effects of saline implants, received their implants for reconstruction after mastectomy.

It's not improbable. There is a biological plausibility to the question of whether or not breast cancer survivors may be at increased risk for some health problems caused by implants as compared to other women.

There might be health problems. It's possible that there could be health problems that are specific to breast cancer survivors, but we won't know that question, the answer to those questions, unless the FDA and you give the advice to the FDA to require that the manufacturers look at that question, and the answer will take what it takes to answer any

scientific and clinical question like this: trials with adequate sample size to determine an effect.

We heard results of meta analyses. We heard a guesstimate of what percent of women were in those meta analyses and in a statement that we should infer that the women had no risk -- in this case it was of connective tissue disorder -- because the overall group had no risk, but we all know, even we in the consumer world, that if there weren't enough women with saline implants to answer that question, the fact that they don't affect the overall outcome doesn't prove that you've answered any question about the impact on their health.

So I'm deeply troubled, and as our breast cancer specific groups -- I know that the agency has received a letter from Breast Cancer Action in San Francisco expressing this concern, that there is this possibility that any of these implants could be approved for use in reconstruction after mastectomy without adequate studies.

We are more than anything concerned with the lack of long term follow-up. It's been 15 years

since your predecessors on this panel first recommended to the FDA that the manufacturers conduct studies and provide sound data assuring the safety and effectiveness of these devices.

It's been 12 years since the FDA accepted that recommendation and informed the manufacturers that such data would be required, and it has been eight years sine this panel found the available data wanting and engaged other research bodies in trying to stimulate needed research.

There's absolutely no excuse for us not to have solid data on the long term effects of these devices in year 2000.

Another concern we have is the loss to follow-up rate. We don't know what it is now. We haven't seen the studies that you reviewed in advance and will be presented this afternoon, but loss to follow-up, it's a frightening prospect for us out in the consumer world.

If the loss to follow-up is higher than average in the type of trials you're used to seeing, we would wonder based on the anecdotal reports of

women in support groups who say they've talked to this woman, that woman and another woman who either has never been followed up or who has had her surgeon assume that her reported complications are not related to her device. We would be worried about selective loss to follow-up, and we hope that the FDA would have -- the FDA staff will be able to report to us later this afternoon that as they've examined the case reports and the manufacturer's submissions very carefully, that they've looked at and verified the procedures that have been used for follow-up.

So we hope that you'll give that really serious attention this afternoon and tomorrow.

And to wrap up, I'd just like to say as the representative of a consumer group that works on a multiplicity of women's health issues, we know that the term "FDA approved" carries great weight with the public. These implants currently have the sort of aura of approval just because they've been in existence and been used so widely for so long.

But if the panel votes to recommend approval for any of the saline filled breast implants

being considered today, women will even more so believe that these devices have been proven to be safe.

Women count on the FDA to protect their health, and we believe and urge you to consider that approving a device such as this, without long term safety data and without data that specifically demonstrated safety in the populations in which it will certainly be used would be a betrayal of that trust that women place in the FDA.

We urge you to take these concerns into consideration as you evaluate whether the data before you are sufficient to warrant approval.

Thank you.

CHAIRMAN WHALEN: Dr. Burkhardt?

DR. BURKHARDT: If you don't mind, a question. One thing I did not -- could not follow. I was unable to follow your apparent criticism of the statistical studies, many of which we'll rely on specifically in regard to meta analysis.

Can you explain that to us?

MS. PEARSON: Yes. Before the FDA acted

in the early 1980s -- excuse me -- the early 1990s to restrict access to silicone gel filled implants, they were by far the most common type of breast implant used.

The meta analysis, like all of the previously published studies for the most part included the general population of users identified in a variety of ways, but unless the study was -- a particular study was designed specifically to include women with saline filled implants, their study population would reflect the general population, which was more than three-quarters women with silicone gel filled implants.

Dr. Ory said that when he was asked what is the relative risk of I believe it was connective tissue disease after using -- in women with saline filled implants as compared to a woman with no implants at all, he said that the overall risk is close to one. The risk for women with silicone gel filled implants is close to one in those studies which separated them.

So since those two risks are both one, we

can infer that the relative risk for women using saline must be close to one.

My point is if there weren't enough women with saline filled implants in those studies to come up with a population size that has the power to find a relative risk of something like connective tissue disorder, which is relatively rare in the general population, the fact that the inclusion of some few number of women with saline filled implants did not change the grand total relative risk does not tell you one way or another whether or not those women are affected by their implants.

I believe, and I think you'll have your hands on more of the numbers to know specifically, and you'll have saline specific studies submitted by the manufacturer, but I believe that until now the majority of published studies don't have the sample size of users of saline filled implants to answer very many questions at all.

DR. BURKHARDT: Can you think of any reason one would suspect the incidence of systemic problems to be greater with the silicone implants --

with the saline implants than with the gel implants?

MS. PEARSON: Not necessarily, but as a representative of a consumer organization, I believe that these devices should be held to the same standards that they would have been held to if they came to the agency after the device amendment passed in 1976.

The fact that they existed before '76 allowed the situation to emerge that we have now, where we have decades of use, and I believe that you would only ask that question if you had the opinion based on clinical experience in decades of use that you know something about saline filled implants.

We would like the opinions that have been believed up until now to be verified by trials of the size and design that can get the answer to those questions.

DR. BURKHARDT: Thank you.

MS. PEARSON: Another question?

(No response.)

MS. PEARSON: Thank you very much.

CHAIRMAN WHALEN: Thank you.

Next we'll hear from Ms. Martha Murdock from the National Silicone/Saline Implant Foundation.

MR. HAYTON: I'm Ron Hayton. Martha was sick this morning so I got volunteered.

We have no connection with the manufacturers, no money except from my regular job.

I'd like to discuss a few issues for the panel to consider when making recommendation for PMA -- thank you. I would like to discuss a few issues for the panel to consider when making recommendation for PMA approval of saline breast implants.

Thank you for providing an opportunity to do so.

First, I'd like to quote a couple of paragraphs from a recent article published January 24th of this year, copyrighted by Healthion Web, M.D. I chose this article because of these types of comments repeatedly.

The article states regarding the advisory hearing, underlying the meetings are very clear indications that the FDA is in favor of approving saline filled implants, products that while available

for a quarter of a century have never been approved by the agency.

A decision to formally approve silicon gel implants which are more controversial than saline implants will come later, but all indications are the FDA is favorably disposed to approving them as well.

The article further states a recent letter sent by the FDA to a member of Congress declared that the agency feels that there is a need not only for saline implants, but also for silicone gel implants, at least for reconstruction follow breast cancer surgery.

Saline filled breast implants are not adequate for all women, the letter stated. There continues to be a public health need for silicone filled implants.

The letter was sent to Representative Thomas Bliley, Republican from Virginia, Chairman of the Commerce Committee which oversees FDA activities.

As you see, the buzz is that the PMAs will be approved. The FDA implies that Congress wants implants to remain on the market because they are a

medical necessity. They fill a public need, and women should have the right to choose what she does with her body as long as she gives informed consent.

I'm sure you'll hear these statements many times by those who wish to keep breast implants on the market. I am in agreement with most of these general concepts, but I think there are a few things to consider.

It is my hope that what Congress wants is for the FDA to fulfill its duty to provide protection to the consumers that only safe, effective products will be marketed in the United States. It has become increasingly obvious that failure rates for breast implants is much higher in companies' reports. Recently published research indicates 25 to 30 percent women will need additional surgery in five years. Putting that into perspective and relating it to human beings, that means of 150,000 women a year receiving breast implants, 45,000 women will have to endure additional surgery with all of the risks and expenses involved with any surgery.

I ask you as American consumers: do we

wish to set a standard that a 30 percent failure rate of a product in five years is acceptable? Is this a standard that is acceptable to the FDA?

In 1993, FDA Commissioner David Kessler stated that a five percent failure rate was not a failure rate that the FDA could accept for this device.

Dr. Laurie Brown, a FDA researcher, has done a comprehensive study on the rupture rate of silicone implants. It's been done for quite some time, but has not been published. I suspect that that is because she has found unbelievably high failure rates for these devices.

I believe the FDA has an obligation to make this data available to the public and certainly to this panel. Although Dr. Brown's research reported failure rates exclusively for silicone implants, one could easily conceive failure rates for saline implants would be the same or higher.

Saline implants are manufactured with the same silicone bag or shell as silicone implants. Additionally, they have valves that have been known to

leak and fail at unbelievably high rates.

And finally, because sometimes are under filled, the risk of crease fold failures is increased.

Another paragraph from this article states that in the letter to Bliley, FDA said that it believes that women can evaluate risk versus the benefits of breast implants for their personal situation if they are well informed about the rate of infection and other local complications that can occur.

The agency cited a study in the New England Journal of Medicine published March 1997 that found infections occurred in 2.5 percent of the women undergoing implants; other local complications, including rupture, pain, and disfigurement. All of these may lead to medical interventions and repeat surgery, the letter stated.

In the letter to Chairman Bliley, the FDA conveniently left out the information from the same study which stated that approximately 25 percent of the women studied required additional surgery in the first five years, and the reconstruction patients had

higher complication rates than cosmetic patients.

One thing you don't hear much about is the companies that have numerous problems with their manufacturing processes. It is evidenced by FDA Form 483 inspection reports for both Mentor and McGhan since the moratorium in 1992 for most breast implant manufacturers prior to the moratorium.

Inspection reports reveal quality control problems, the under reporting of complications, and the inability to validate manufacturing processes of these devices. In fact, the FDA had to resort to issuing a consent decree against Mentor in 1998 just to get them to comply with the law as good manufacturing practices, and to insist the company validate its manufacturing processes.

The bottom line is companies are having problems proving their devices are safe and effective. Former company employees have reported company data may be misleading and problems with devices are not adequately addressed and corrected. Could it be they can't prove the products are safe and effective?

A thorough investigation would probably

shed light onto why company data is significantly different than published data regarding complications.

I urge the panel members to review FDA 483s and their EIR reports for the past 15 years for each company submitting a PMA before recommending approval. I am providing you with samples for your review.

I'd like to briefly address the issues the manufacturers and breast implant advocates argue for PMA approval, along with my responses to these statements. Additionally, I'd like to provide you with a copy of Mentor's PR plan titled "Mentor v. the World," which may give you an indication of where some of these myths may have originated.

Myth number one, breast implants are medically necessary.

Response: breast implants are not medically necessary. They are not required for body functions.

Myth two, breast implants fulfill a public need.

I believe it could be argued that breast

implants fulfill a public desire for reconstruction patients, but there is not a public need for those who simply -- for cosmetic reasons. Surprisingly, only 15 to 20 percent of the women who have received breast implants do so for reconstruction.

These people may be willing to take the risk for what they perceive as a benefit they may receive and are entitled to make their own choice, if and only if they are given all of the information. Would you choose a breast implant from a company who has been cited for repeated violation of good manufacturing practices, or if you knew they were undergoing criminal investigation, or if you knew by having breast implants or if you've had breast implants many health insurance companies will deny you coverage?

CHAIRMAN WHALEN: Mr. Hayton, I'll have to ask you to come to a conclusion, please.

MR. HAYTON: I thought I had ten minutes.

CHAIRMAN WHALEN: Indeed, you do, but that light is flashing.

MR. HAYTON: Oh. Well, I'll just leave it